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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,789	10/11/2005	Henri Tiedge	1181-13 PCT US	2634

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EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,789	TIEDGE, HENRI	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-18* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/2009 has been entered.

Status of Application/Amendment/Claims

Applicant's response filed 2/12/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 10/8/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment to the claims filed 2/12/2009 is acknowledged. With entry of the amendment, claims 1-6 and 8-18 are pending.

Claims 5, 6, and 8-16 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4, 17, and 18 are under consideration.

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 17, and 18 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of Tiedge et al. (U.S. Patent No. 5,670,318).

U.S. Patent 5,670,318 claims oligonucleotide probes that are identical to instantly claimed antisense sequences SEQ ID NO:3 and 4. See claims 2 and 3. US Patent 5,670,318 further generically claims oligonucleotide probes that hybridize to residues 156-185 of a BC200 RNA target sequence, referred to therein as SEQ ID NO:1, that is identical to instantly recited SEQ ID NO: 1. Accordingly, US Patent 5,670,318 necessarily also claims probes that hybridize to instantly recited SEQ ID NO:2. Thus, the probes claimed in US Patent 5,670,318 are

structurally identical to the antisense sequences claimed in the instant application, and, therefore, possess all properties inherent to such sequences, whether recognized at the time or not.

With regard to instant claims 17 and 18, drawn to kits comprising said antisense molecules, it was well known in the prior art to package probes and other diagnostic reagents, routinely used in the laboratory, in the form of kits to save time and expense. Further, the term "Kit" is not limited by either the claims or the specification to commercially purchased materials but is broadly interpreted to include any compartmentalized arrangement of the probes in enclosed vessels and/or carriers prepared by the artisan according to routine practice.

Absent evidence to the contrary the carriers used to prepare and store probes, which typically consist of buffered dilute aqueous solutions at or near physiological pH, would be "acceptable" within the scope of the claims.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Therefore, one of ordinary skill in the art would conclude that the invention defined in the claims at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the conflicting patent.

***

Claims 1-4, 17, and 18 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of Tiedge et al. (U.S. Patent No. 5,736,329).

U.S. Patent No. 5,736,329 claims methods for testing for the presence of Alzheimer's disease using oligodeoxynucleotide probes that hybridize to BC200 RNA. In certain embodiments, claims 3 and 4, the probes used in the method are identical to instant antisense sequences SEQ ID NO:3 and 4, and would therefore possess all properties inherent to such sequences.

Kits containing these probes are prima facie obvious, since it was normal practice in the art to prepare and store reagents beforehand for convenience and ease of use in later experiments. Carriers used for the preparation of probes would be indistinguishable from those used for the preparation of antisense.

Therefore, one of ordinary skill in the art would conclude that the invention defined in the claims at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the conflicting patent.

***

Claims 1-4, 17, and 18 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-19 of copending US Patent Application 10/503782, now U.S. Patent 7,510,832 in view of Tiedge (US Patent 5,670,318).

Copending Application 10/503782 claims methods for testing whether a breast carcinoma has an invasive phenotype comprising combining the test sample with an oligonucleotide probe capable of hybridizing with human BC200 RNA.

Tiedge et al. taught probes capable of hybridizing to BC200 RNA identical to instant SEQ ID NO:1 for detection and diagnostic purposes. The probes used for such methods would necessarily comprise all properties inherent to such sequences.

Tiedge et al. further taught kits comprising these probes, including the specific probes comprising instant SEQ ID NO: 3 and 4 for detecting BC200 RNA (col. 3 and 5).

Therefore, one of ordinary skill in the art would conclude that the invention defined in the claims at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the conflicting patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 17, and 18 are rejected under 35 U.S.C. 102(b) as being unpatentable over Tiedge et al. (US Patent 5,670,318).

Tiedge et al. disclosed oligonucleotide probes that hybridize to a BC200 RNA target sequence identical to instant SEQ ID NO:1 for diagnostic purposes (cols. 1-5). In certain embodiments the probes are identical to instantly claimed antisense sequences SEQ ID NO:3 and 4 (see the sequences set forth at the top of column 3). Additionally, Tiedge et al. specifically taught probes complementary to instant SEQ ID NO:2 (see column 2, bottom). Tiedge et al. further taught kits comprising these probes, including the specific probes comprising instant SEQ ID NO: 3 and 4 for detecting BC200 RNA (col. 3 and 5).

While Tiedge et al. do not specifically teach using these probes for inhibition of BC200 RNA expression, the sequences are identical to the "antisense" sequences now claimed.

Therefore, all properties inherent to these sequences, whether recognized or not, were disclosed and in the public domain more than one year before the filing date of the instant application. Because the disclosed sequences are identical to those now claimed in claims 3 and 4, the disclosed sequences necessarily possess antisense properties and *de facto* are antisense to the target recited in instant claims 1 and 2. For example, instant SEQ ID NO:4 is identical to SEQ ID NO:7 in Tiedge et al., which specifically hybridizes with instant SEQ ID NO:1 and 2, also identical to SEQ ID NOs. 1 and 2, respectively in Tiedge et al.

[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Applicant is not claiming a method of use, but the product itself. The term "antisense", used in the instant claims, is merely an intended use that does not clearly impose any structural limitations distinguishable from those sequences set forth by Tiedge et al. Thus, the probes disclosed by Tiedge et al. are structurally indistinguishable from the sequences now claimed.

Tiedge et al. further taught the oligonucleotide probes of their invention could be synthesized using conventional chemical synthetic methods known in the art (col. 4, lines 5-10). At the time of invention it was normal laboratory practice to elute, resuspend, and store chemically synthesized oligonucleotide probes in diluents such as distilled water or Tris buffer, which would, absent evidence to the contrary, would be "acceptable" carriers for antisense.

Accordingly, the mere formulation of the claimed antisense molecules in an acceptable carrier does not patentably distinguish the claimed compositions over those disclosed by Tiedge et al., since the probe compositions disclosed by Tiedge et al. are structurally indistinguishable from those now claimed.

Response to arguments

Applicant argues the instantly claimed antisense molecules are patentably distinct from the probes disclosed by Tiedge et al. because the claimed antisense are in an "acceptable carrier." However, neither the claims nor the specification explicitly define what solvents are specifically included or excluded by the limitation "acceptable carrier" and Applicant provides no evidence any of the diluents or buffers which would have routinely or commonly been used by one of ordinary skill the art to prepare, store, or use the probes disclosed by Tiedge et al. would not be "acceptable" within the scope of this limitation. If it is Applicant's opinion buffers normally used in the art at the time of the Tiedge et al. disclosure to isolate and store probes, such as Tris-EDTA or doubly distilled water, are not acceptable for antisense, the Examiner respectfully disagrees.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
April 1, 2009